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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,747	10/10/2003	Pieter Jurjen Groenewoud	M009.P005U1	2830

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EXAMINER	
HUYNH, CARLIC K	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
08/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/683,747	GROENEWOUD ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks filed on May 21, 2007 is acknowledged.

Status of the Claims

1. Claims 1-12 are pending in the application, with claims 13-22 having been cancelled in an "Amendment – After Non-Final Rejection" submitted on May 21, 2007. Accordingly, claims 1-12 are being examined on the merits herein.

Response to Arguments

2. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on May 21, 2007, with respect to "Rejections under 35 U.S.C. § 112, 2nd paragraph" to claims 1 and 10 and to claim 4 has been fully considered and are persuasive. As cited in MPEP 2173.05(b) (D), the use "substantially" does not render a claim indefinite. Applicant's arguments and exhibits have been persuasive to conclude that the terms "dry compaction" and "dry granulators" are well known in the art to be a part of the "dry granulation" process. Thus, the Rejections under 35 U.S.C. § 112, 2nd paragraph to claims 1 and 10 and to claim 4 for being indefinite have been withdrawn in light of the arguments.

3. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on May 21, 2007, with respect to "Rejections under 35 U.S.C. § 102" to claims 1-2 and 4-11 has been fully considered and are persuasive. Kushla et al. (US 6,348,216) does not specifically teach the dry granulation process. Thus, the Rejections under 35 U.S.C. § 102 to claims 1-2 and 4-11 have been withdrawn in light of the arguments.

4. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on May 21, 2007, with respect to "Rejections under 35 U.S.C. § 103" to claims 3 and 12 has been fully considered and are not found persuasive. Kushla et al. (US 6,348,216) do not teach dry granulation but rather it teaches wet granulation. Arnold (US 4,587,252) teaches pharmaceutical compositions of hydrocodone-ibuprofen in tablet and capsule dosage formulations. However, it is well known in the art that wet granulation and dry granulation are well known methods of making solid pharmaceutical dosage forms (e.g. tablets and caplets). Thus, the Rejections under 35 U.S.C. § 103 to claims 3 and 12 have been maintained.

5. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection. The following new ground(s) of rejection to claims 1-12 are used herewith.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kushla et al. (U.S. Patent No 6,348,216) in view of Arnold (U.S. Patent No. 4,587,252) as evidenced by Summers et al. (Pharmaceutics: The Science of Dosage Form Design" 2nd ed. Chapter 25. pp.364-378).

Regarding "dry powder phase" in claim 1, step (a) and claim 10, step (a), given their broadest interpretation, the claim read on a powder form of ibuprofen, a narcotic analgesic, and at least one excipient.

Kushla et al. teach a method of granulating ibuprofen and a narcotic analgesic to form granules, blending the granules into a blend of granules, and compressing the blend to form tablets (column 3, lines 35-44). The granulation step is performed using a wet granulation process (column 3, lines 37-38).

Kushla et al. also teach various excipients such as croscarmellose sodium, microcrystalline cellulose, and magnesium stearate (column 6, table 1), the incorporation of the excipients in the tablet production process (column 4, lines 50-58, for example), hydrocodone bitartate as the narcotic analgesic (column 2, line 9), and the amount of ibuprofen and hydrocodone bitartate in each tablet (column 4, lines 63-64).

Kushla et al. do not teach a caplet dosage form.

Arnold teaches hydrocodone-ibuprofen compositions as tablet or caplet dosage forms (column 2, lines 46-47). Arnold further teaches the hydrocodone-ibuprofen composition was made by mixing batches of the ingredients and filling hard gelatine capsules with the mixture (column 4, lines 53-55). Thus, it is obvious the hydrocodone-ibuprofen composition of Arnold et al. was made by either a wet or dry granulation process since the ingredients were mixed and then filled to form capsules.

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the method of Kushla et al. to make caplets because the composition of Arnold is an ibuprofen-narcotic analgesic

pharmaceutical composition and according to Arnold, caplets can be made of an ibuprofen-narcotic analgesic pharmaceutical composition.

The motivation to combine the method of Kushla et al. to the caplets of Arnold is that the composition of Arnold is an ibuprofen-narcotic analgesic pharmaceutical composition in caplet dosage forms.

Regarding dry granulation as recited in claims 1 and 10, the wet granulation process taught by Kushla et al. is obvious over the dry granulation process in the instant claims. As evidenced in Summers et al., wet and dry are the methods of granulation (page 366). In dry granulation, the primary powder particles are aggregated under high pressure, e.g. by roller compaction (page 366). In wet granulation, a mix of dry primary powder particles using a granulating fluid (page 366). The granulating fluid used in wet granulation are organic solvents "when water-sensitive drugs are processed, as **an alternative to dry granulation**, or when a rapid drying time is required" (pages 366-367).

Regarding claim 10, step (d), "adding, extra-granularly, a narcotic analgesic to the dry granules", it is obvious over the method taught in Kushla et al. It is noted that "It has been held that merely reversing the order of steps in a multi-step process is not a patentable modification absent unexpected or unobvious results". *Ex parte Rubin*, 128 U.S.P.Q. 440 (P.O.B.A. 1959). *Cohn v. Comr. Patents*, 251 F. Supp. 437, 148 U.S.P.Q. 486 (D.C. 1966).

Conclusion

7. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

SHENGJUN WANG
PRIMARY EXAMINER